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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,244	07/23/2003	Nicholas V. Perricone	00961-P0213A	3183
24126	7590	12/16/2005	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 12/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/625,244

**Applicant(s)**

PERRICONE, NICHOLAS V.

**Examiner**

Simon J. Oh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 25 November 2005.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 12 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 10-18 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Runge *et al.* and Woerwag *et al.* is maintained.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Runge *et al.* (U.S. Patent No. 6,261,598 B1) and Woerwag *et al.* (German Patent Application Publication No. DE 41 10087 A1)

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The Runge *et al.* patent teaches carotenoid formulations for use in foods, cosmetics, and pharmaceuticals (See Abstract). The formulations may contain 0.01% to 40% by weight of various ingredients and combinations thereof, including vitamins such as tocotrienol, and allithamines, such as benfotiamine (See Column 2, Lines 41-61; and Column 3, Lines 3-4). The formulations may comprise other ancillary substances and additives, such as physiologically acceptable oils (See Column 3, Lines 8-18). Minor amounts of stabilizers may also be added, such as  $\alpha$ -tocopherol and ascorbic acid (See Column 3, Lines 31-41). Emulsifiers or solubilizers such as lecithin may also be added from 0% to 200% by weight of the carotenoids included in the formulation. Cosmetic formulations according to the disclosed invention include topical preparations, such as creams, lotions, emulsions, and suspensions (See Column 4, Lines 33-38).

The Runge *et al.* patent does not explicitly teach methods of treating skin damage.

The Woerwag *et al.* document discloses benfotiamine formulations comprising a carrier and applied topically to the skin for the treatment of various disorders, such as rheumatic disorders, and shingles.

It would be obvious to one of ordinary skill in the art to combine the prior art references in order to obtain the instantly claimed invention. As both references disclose topical compositions containing benfotiamine and auxiliary ingredients, it is the position of the examiner that one of ordinary skill would find it obvious to combine the prior art references, and that the composition arising from the collective disclosure of the prior art would contain the benefits found in each reference. The composition disclosed in the Runge *et al.* patent reads upon the breadth of the instant claim language, and furthermore discloses the composition as being useful as a cosmetic. It is the position of the examiner that one of ordinary skill in the art would, in

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light of such a disclosure, attribute the cosmetic composition as being useful for treating or preventing skin aging, with a reasonable expectation of success. The Woerwag *et al.* document discloses that the benfotiamine compositions are useful for treating rheumatic disorders and shingles, conditions that are known in the art to cause damage to skin. Therefore, one of ordinary skill in the art would be able to use the compositions of the prior art to treat or prevent skin damage with a reasonable expectation of success.

Thus, the instantly claimed invention is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 25 November 2005 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The basis for the applicant's arguments against the Runge *et al.* reference is unclear. If Runge *et al.* had taught each and every element of the present claims, then the examiner would have surely by now applied that reference against the instant claims under 35 U.S.C. 102. Despite what the applicant alleges to be a mere cursory disclosure of benfotiamine, it is still fairly taught within the broad disclosure of the prior art. Thus, the disclosure of benfotiamine in the prior art remains valid and is fairly applied against the instant claims. See MPEP § 2111 and 2123.

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As previously stated by the examiner, there exists an overlap in the patient populations between those that would likely be treated by the instantly claimed methods and those of the prior art suffering from rheumatic disorders and shingles, who are more likely to be middle-aged or elderly. Thus, such patients would be likely to benefit from the administration of benfotiamine, whether it is for the treatment of rheumatic disorders and shingles or for the reduction of the appearance of aging on their skin.

As the prior art has shown methods of treatment that comprise the administration of benfotiamine for the treatment of diseases and conditions that manifest in symptoms of irritation or inflammation of the skin, it is therefore the position of the examiner that the instantly claimed invention is implicitly and inherently disclosed by the prior art. With respect to the instantly recited function of reducing the presence of glycated proteins, the applicant has not yet shown how this function is not merely a new property of previously known methods and compositions of the prior art. Therefore, the examiner must maintain the prior art rejection of record. See MPEP § 2112.

Thus, all pending claims remain rejected.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

sj0

  
MICHAEL HARTLEY  
PRIMARY EXAMINER